

EXPRESS MAIL LABEL NO. EV 546 123 163 US  
DOCKET NO. CCS 5002USPCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : BACHMANN et al.

Serial No. : Not Assigned

Art Unit: Not Assigned

Filed : Herewith

Examiner: Not Assigned

For : CONTROLLED RELEASE PREPARATIONS COMPRISING  
TRAMADOL AND TOPIRAMATE

Commissioner for Patents  
Alexandria, VA. 22313

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)),

within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee.

Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ There are no listed references which are not in the English language.

☒ The relevance of those listed references which are not in the English language is as follows: We have provided a full translation of EP 0914 823 B1 and Frankus E. et al., Arzneim-Forsch. Drug. Res., pages 114-121.

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D. With the exception of one article, "K. Kralinsky E.A., Elsevier Science Publishers,

JC09 Rec'd PCT/PTO 13 JUN 2005

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vol. 7, no. 6, 1994, pages 182-185" which will follow at our earliest opportunity.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/CCS5002USPCT/MBZ. This form is submitted in triplicate.

Respectfully submitted,

/Matthew B. Zisk/  
Matthew B. Zisk,  
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Attorney for Applicants

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DATED: June 13, 2005

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary) Sheet 1 of 1	<b>Application Number</b>	Not yet Assigned
	<b>Filing Date</b>	Herewith
	<b>First Named Inventor</b>	Dieter Bachmann
	<b>Group Art Unit</b>	Not yet Assigned
	<b>Examiner Name</b>	Not yet Assigned
	<b>Attorney Docket Number</b>	CCS 5002USPCT

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
		3,652,589		Chemie Grunenthal	03-28-1972	
		4,513,006		McNeil Lab., Inc.	04-23-1985	
		5,143,763		Toray Industries, Inc.	09-01-1992	
		5,336,691		McNeilab, Inc	08-09-1994	
		5,415,871		The Boots Co. PLC	05-16-1995	
		5,427,799		Valentine Enterprises, Inc.	06-27-1995	
		5,468,744		McNeilab, Inc.	11-21-1995	
		5,516,803		McNeilab, Inc.	05-14-1996	
		5,760,007		Ortho Pharmaceutical Corp.	06-02-1998	
		6,207,197	B1	West Pharm. Serv. Drug Deli. & Clin. Res. Ctr. Ltd.	03-27-2001	
		US2004/0266951	A1	Akiyama et al.	12-30-2004	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup>				
		EP	0699436	B1	Euro-Celtique S.A.	04-29-1994		
		WO	96/06822	A1	Zeneca Ltd.	03-07-1996		
		WO	98/06708	A1	G.D. Searle & Co.	02-19-1998		
		WO	01/13904	A2	Ortho-McNeil Pharm. Inc.	03-01-2001		
		EP	1364649	A1	Cilag AG	05-23-2002		
		EP	0914823	B1	Janssen Pharmaceutica N.V.	05-11-1998		✓
		WO	2004/054571	A1	Cilag AG	07-01-2004		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published, city and/or country where published	T <sup>2</sup>
		FRANKUS, V. E. et al. "Concerning the Separation of the Isomers of 1-(m-methoxyphenyl)-2-(dimethylaminomethyl)-cyclohexan-1-ol, their Structural Elucidation, and their Pharmacological Characterization." <i>Ameim-Forsch. Drug. Res.</i> , 1978, pages 114-121, vol. 28, no. 1.	✓
		GROUND, S. et al., "Weak opioids -an educational substitute for morphine? <i>Current Opinion in Anaes.</i> , 1998, pages 559-565, XP000982759.	
		OBAIDAT, A. et al., "Controlled release of tramadol hydrochloride from matrices prepared using glyceryl behenate." <i>Euro. J. Pharm. Bioph.</i> , 2001, pages 231-235, vol. 52.	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Alexandria, VA 22313-1450.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Alexandria, VA 22313-1450.

<b>SUBMISSION UNDER MPEP 609 D</b>  <b>Page 1 of 1</b>	<i>Application Number</i>	Not yet Assigned
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	<i>Examiner Name</i>	Not yet Assigned
	<i>Attorney Docket Number</i>	CCS 5002USPCT

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			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PCT International Search Report dated March 19, 2001 for PCT Application. No. PCT/US00/21622 which relates to U.S. Patent Application filed herewith.	

Examiner Signature	Date Considered	
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